

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

THE UNITED STATES OF AMERICA *ex rel.*
AZAM RAHIMI, RADIF RASHID, et al.,

Plaintiffs,

v.

ZYDUS PHARMACEUTICALS (USA) INC.,
et al.,

Defendants.

Civil Action No. 3:15-cv-06536-BRM-DEA

Electronically Filed

Oral Argument Requested

Return date: June 5, 2017

**MEMORANDUM IN SUPPORT OF DEFENDANT ZYDUS
PHARMACEUTICALS (USA), INC.'S MOTION FOR
RECONSIDERATION OF APRIL 26, 2017 ORDER**

BLANK ROME LLP

A Pennsylvania LLP

STEPHEN M. ORLOFSKY

NICHOLAS C. HARBIST

DAVID C. KISTLER

New Jersey Resident Partners

301 Carnegie Center, 3rd Floor

Princeton, NJ 08540

Telephone: (609) 750-2646

Facsimile: (609) 897-7286

KIRKLAND & ELLIS LLP

JENNIFER G. LEVY (*pro hac vice*)

JASON R. PARISH (*pro hac vice*)

655 Fifteenth Street, NW

Washington, DC 20005

Telephone: (202) 879-5000

Facsimile: (202) 879-5200

Attorneys for Defendant Zydus Pharmaceuticals (USA), Inc.

TABLE OF CONTENTS

	Page
PRELIMINARY STATEMENT	2
RELEVANT BACKGROUND	3
LEGAL STANDARD.....	5
ARGUMENT	5
I. RELATORS HAVE NOT ALLEGED PRESENTMENT.	5
II. CERTAIN OF RELATORS' STATE FCA CLAIMS ARE TIME- LIMITED.	7
III. RELATORS LACK STANDING TO PROCEED WITH THEIR STATE FCA CLAIMS.....	10
A. Three States—Georgia, Hawaii, and Rhode Island—Have Not Filed Notices Declining Intervention.	11
B. The Notices Declining Intervention Filed by 24 States and the District of Columbia Do Not Comply with State FCA Requirements.	12
CONCLUSION.....	20

TABLE OF AUTHORITIES

	Page(s)
Cases	
<i>United States ex rel. Bogart v. King Pharms.</i> , 414 F. Supp. 2d 540 (E.D. Pa. 2006)	19
<i>Brackett v. Ashcroft</i> , No. 03-3988, 2003 WL 22303078 (D.N.J. Oct. 7, 2003)	5
<i>Cole v. Silverado Foods, Inc.</i> , 78 P.3d 542 (Okla. 2003)	9
<i>DeLong Corp. v. Raymond, Int’l Inc.</i> , 622 F.2d 1135 (3d Cir. 1980)	5
<i>Direct Action for Rights & Equal. v. Gannon</i> , 819 A.2d 651 (R.I. 2003)	10
<i>Enfield Fed. Sav. & Loan Ass’n v. Bissell</i> , 440 A.2d 220 (1981)	8
<i>United States ex rel. Foglia v. Renal Ventures Mgmt., LLC</i> , 754 F.3d 153 (3d Cir. 2014)	2, 6
<i>Fowler Props., Inc. v. Dowland</i> , 646 S.E.2d 197 (Ga. 1997)	8
<i>Max’s Seafood Café ex rel. Lou-Ann, Inc. v. Quinteros</i> , 176 F.3d 669 (3d Cir. 1999)	5
<i>Mason v. Farmers Ins. Cos.</i> , 281 N.W.2d 344 (Minn. 1979)	9
<i>Olkusz v. Brown</i> , 951 A.2d 1069 (N.J. Super. Ct. App. Div. 2008)	9
<i>Robinson v. Valladares</i> , 738 N.E. 2d 278 (Ind. Ct. App. 2000)	9
<i>United States ex rel. Simpson v. Bayer Corp.</i> , No. 05-3895, 2014 WL 1418293 (D.N.J. Apr. 11, 2014)	19

<i>United States ex rel. Tex. Portland Cement Co. v. McCord</i> , 233 U.S. 157 (1914).....	19
---	----

Statutes

31 U.S.C. § 3730(b)(4)(B)	3
Cal. Gov't Code § 12652(c)(3)	12, 17
Cal. Gov't Code § 12652(c)(5)	18
Cal. Gov't Code § 12652(c)(6)	14, 18, 19
Colo. Stat. § 25.5-4-306(2)(b).....	12
Colo. Stat. § 25.5-4-306(2)(d).....	14
Conn. Gen. Stat. § 17b-301d(b).....	12, 14
D.C. Code § 2-381.03(b)(3).....	12
D.C. Code § 2-381.03(b)(4).....	14, 15
Del. Code § 1203(b)(2).....	12
Del. Code § 1203(b)(4).....	14
Fla. Stat. § 68.083(3).....	12
Fla. Stat. § 68.083(6).....	15
Ga. Code § 49-4-168.2(4)	15
Ga. Code § 49-4-168.2(c)(1).....	12
Ga. Code § 49-4-168.2(c)(4).....	11
2007 Ga. Laws Act 220, § 4	9
Haw. Stat. § 661-25(b).....	12
Haw. Stat. § 661-25(d).....	11, 15
Ill. Comp. Stat. 175/4(b)(2).....	12
Ill. Comp. Stat. 175/4(b)(4).....	15
Ind. Code § 5-11-5.5-4(c)	13
Ind. Code § 5-11-5.5-4(c), (e).....	14, 15

2005 Ind. Legis. Serv. P.L. 222-2005, § 23	9
Iowa Code § 685.3(2)(b).....	13
Iowa Code § 685.3(d)	15
Mass. Gen. Laws ch. 12 § 5C(3).....	13
Mass. Gen. Laws ch. 12 § 5C(4).....	14, 15
Mich. Comp. Laws § 400.610a(2)	13
Mich. Comp. Laws § 400.610a(3)	14, 16
2009 Minn. Sess. Law Serv. Ch. 101, § 25.....	9
Minn. Stat. § 15C.05(e).....	13
Minn. Stat. § 15C.06(a).....	16
Mont. Code § 17-8-406(2)	13
Mont. Code § 17-8-406(3)	16
N.C. Gen. Stat. § 1-608(b)(2)	13
N.C. Gen. Stat. § 1-608(b)(4)	14, 16
N.H. Rev. Stat. § 167:61-c(II)(c)	13
N.H. Rev. Stat. § 167:61-c(II)(e)	16
2007 N.J. Sess. Law	9
N.J. Stat. § 2A:32C-5(d)	13
N.J. Stat. § 2A:32C-5(g)	16
N.M. Stat. § 44-9-5(C).....	13
N.M. Stat. § 44-9-5(D).....	16
N.Y. State Fin. Law § 190(2)(b).....	13
N.Y. State Fin. Law § 190(2)(c)	16
N.Y. State Fin. Law § 190(2)(f).....	16
Nev. Rev. Stat. § 357.080(5).....	13

Nev. Rev. Stat. § 357.110(1).....	16
New Jersey False Claims Act	9
2007 Okla. Sess. Law Serv. Ch. 137, § 9.....	10
Okla. Stat. tit. 63 § 5053.2(B)(2)	14
Okla. Stat. tit. 63 § 5053.2(B)(4)	17
R.I. Gen. Laws § 9-1.1-4(b)(2)	14
R.I. Gen. Laws § 9-1.1-4(b)(4)	11, 17
Tenn. Code § 71-5-183(b)(2).....	14
Tenn. Code § 71-5-183(b)(4)	17
Va. Code § 8.01-216.5(B).....	14
Va. Code § 8.01-216.5(D).....	14, 17
Wis. Stat. § 20.931(5)(b).....	14, 17
Wis. Stat. § 20.931(5)(d).....	17
Other Authorities	
Ga Const. art. 1, § 1, ¶ X.....	8
Georgia Constitution.....	8

Pursuant to Local Civil Rule 7.1(i), Defendant Zydus Pharmaceuticals (USA), Inc. (“Zydus”) respectfully requests that the Court reconsider three narrow issues addressed in its April 26, 2017 Opinion and Order denying in part Zydus’s motion to dismiss.

PRELIMINARY STATEMENT

In this action, Relators assert claims under the False Claims Act and the false claims statutes of 28 States and the District of Columbia. In its motion to dismiss, Zydus sought dismissal of Relators’ federal and State claims on multiple grounds, including the three that are the basis for this motion:

First, Relators have not alleged presentment. Under Rule 9(b), Relators must plead “reliable indicia” that false claims were presented to State Medicaid agencies. *See United States ex rel. Foglia v. Renal Ventures Mgmt., LLC*, 754 F.3d 153, 156 (3d Cir. 2014). To satisfy this burden, Relators attached to their Complaint claims submitted by Relator Rashid to New York Medicaid. But these claims—which the Court appears to have misconstrued—do not include the allegedly false AWP’s at issue in this action.

Second, certain of Relators’ State FCA claims are time-limited. The State FCAs of Connecticut, Georgia, Indiana, Minnesota, New Jersey, Oklahoma, and Rhode Island took effect during Relators’ alleged “scheme” and do not have retroactive effect.

Third, Relators lack standing to proceed with their State FCA claims. Three States—Georgia, Hawaii, and Rhode Island—have not filed statutorily-required notices declining intervention. Additionally, the notices filed by other States do not comply with State FCA requirements.

Zydus respectfully requests that the Court revisit each of these issues and reconsider its decision allowing Relators’ claims to proceed.

RELEVANT BACKGROUND

On June 21, 2011, Azam Rahimi filed this *qui tam* action under seal on behalf of the United States, 28 States, the District of Columbia, and the City of Chicago¹ in the United States District Court for the Eastern District of Texas alleging that Zydus violated the False Claims Act, 31 U.S.C. §§ 3729-3732, and State FCAs when it caused the publication of “false” Average Wholesale Prices (“AWPs”) for certain of its generic drugs. *See* ECF No. 1. On December 16, 2011, Mr. Rahimi filed an Amended Complaint (the “Complaint”) stating substantially the same claims and adding Radif Rashid as a relator. ECF No. 9.

On January 23, 2012, the United States filed a Notice of Election to Decline Intervention pursuant to 31 U.S.C. § 3730(b)(4)(B). ECF No. 10. Subsequently, on January 22, 2014, the Eastern District of Texas lifted the seal on this action. ECF

¹ Relators’ claims on behalf of the City of Chicago and certain claims on behalf of the State of Montana have been dismissed from this case. (ECF Nos. 145, 154.) The State of Texas has settled all claims concerning Zydus’s publication of Average Wholesale Prices.

No. 12. As of that date, none of the 28 States or the District of Columbia had filed with the Court notices declining intervention in this action.

On January 9, 2015, Zydus filed a motion to dismiss the Complaint. ECF No. 34. That same day, Zydus filed a motion, in the alternative, to transfer venue to this Court. ECF No. 41. Relators opposed both motions. ECF Nos. 57, 58. On August 6, 2015, the Eastern District of Texas granted Zydus's motion to transfer venue to this Court. ECF No. 81.

On February 3, 2016, Zydus renewed its motion to dismiss the Complaint. ECF No. 101. As in its initial motion, Zydus argued that (i) Relators have not pled "reliable indicia" that false claims were presented to State Medicaid agencies, (ii) many of Relators' State FCA claims are time-limited, and (iii) Relators could not proceed with their State FCA claims because the States had not filed notices declining intervention. ECF No. 101-1 at 25, 33-34.

In September 2016, after the parties completed briefing of Zydus's motion to dismiss, Relators filed with the Court notices declining intervention from 24 States and the District of Columbia. *See* ECF Nos. 120-140, 142-144, 146.

On April 26, 2017, this Court filed an Opinion and Order denying in part Zydus's motion to dismiss. ECF Nos. 153, 154. Zydus now respectfully requests reconsideration of the Court's decision as set forth below.

LEGAL STANDARD

Local Civil Rule 7.1(i) governs motions for reconsideration filed with this Court. Rule 7.1(i) requires the moving party to set forth the factual matters or controlling legal authority it believes the court “overlooked” when issuing its initial decision. L. Civ. R. 7.1(i). While “reconsideration is an extraordinary remedy[] that is granted very sparingly,” *Brackett v. Ashcroft*, No. 03-3988, 2003 WL 22303078, at *2 (D.N.J. Oct. 7, 2003), the decision to grant reconsideration is a matter within the district court’s discretion and may be granted where facts or legal authority were presented by the moving party but overlooked. *See DeLong Corp. v. Raymond, Int’l Inc.*, 622 F.2d 1135, 1140 (3d Cir. 1980), *overruled on other grounds by Croker v. Boeing Co.*, 662 F.2d 975 (3d Cir. 1981). A party seeking reconsideration must show more than a disagreement with a court’s decision; rather, the moving party must show “at least one of the following grounds: (1) an intervening change in the controlling law; (2) the availability of new evidence that was not available ... ; or (3) the need to correct a clear error of law or fact or to prevent manifest injustice.” *Max’s Seafood Café ex rel. Lou-Ann, Inc. v. Quinteros*, 176 F.3d 669, 677 (3d Cir. 1999).

ARGUMENT

I. RELATORS HAVE NOT ALLEGED PRESENTMENT.

Each of Relators’ federal and State FCA claims is founded on the allegation that pharmacies presented false claims to State Medicaid agencies. *See, e.g., Am.*

Compl. ¶¶ 116, 120, 123. Relators allege that the claims were false because they included AWP's that did not reflect the market prices for Zydus's generic drugs. *See, e.g., id.* ¶¶ 79, 84, 111. In support of this allegation, Relators attached to their Complaint ten exhibits, each of which includes an electronic claim form presented by Relator Rashid to New York Medicaid. *Id.* at Exs. 3-12.

In its Opinion, the Court concluded that these exhibits satisfied Relators' burden under Rule 9(b) of alleging "reliable indicia" that false claims were presented to the government:

Exhibits 3 through 12 to the FAC, which are claims submitted by Rashid to New York Medicaid, all clearly show the reported AWP. (See, e.g., ECF No. 9 at Ex. 3 (listing Blue Book's published AWP next to "BBAWP," or "Blue Book Average Wholesale Price".) Thus, the claims and invoices attached to the FAC provide a reliable indicia that false claims were presented to Medicaid.

ECF No. 153 at 23; *see also Foglia*, 754 F.3d at 156 (stating that, pursuant to Rule 9(b), a relator must allege "particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that [false] claims were actually submitted."). However, the Court appears to have misconstrued the exhibits.

The Court's conclusion appears to be premised on the fact that the "claims ... all clearly show the reported AWP." ECF No. 153 at 23. But this is not correct. As is set out in Zydus's motion to dismiss reply brief, Exhibits 3 through 12 each includes two (or more) separate documents: (i) an electronic claim form presented by Relator Rashid to New York Medicaid and (ii) an invoice received by Relator

Rashid from his wholesaler. ECF No. 108 at 10; *see also* Am. Compl. ¶ 57 (“Exhibit 3 contains a specific claim submitted *and* [an] invoice received by Relator Rashid at Fancy Pharmacy for Venlafaxine Hydrochloride Tablets. . . .”) (emphasis added).) While the wholesaler invoices include a figure designated as “BBAWP,” the claims Relator Rashid presented to New York Medicaid do not include the AWP. *See id.* Exs. 3-12. Rather, the only pricing information included in the claims is (1) the patient co-payment/coinsurance amount, (2) the drug ingredient cost, and (3) the billed amount. *See id.* None of this pricing information is alleged to be false, nor does this information correspond to the “BBAWP” that appears in the separate wholesaler invoices. *See id.*

In observing that the “claims . . . all clearly show the reported AWP,” ECF No. 153 at 23, the Court appears to have conflated these separate documents. There is no allegation that Relator Rashid presented the wholesaler invoices to New York Medicaid, and Relators plead no other “reliable indicia” that false claims were presented to State Medicaid agencies. Accordingly, Zydus respectfully requests that the Court reconsider its decision on this issue and dismiss Relators’ claims.

II. CERTAIN OF RELATORS’ STATE FCA CLAIMS ARE TIME-LIMITED.

In its motion to dismiss, Zydus argued that certain of Relators’ State FCA claims are time-limited because (i) Relators allege a “scheme” that began in 2005 and (ii) several of the State FCAs at issue took effect in or after 2005 and do not

have retroactive effect. *See* ECF No. 101-1 at 34. In its Opinion, the Court dismissed with prejudice Relators' claims under the Montana False Claims Act accruing prior to October 1, 2005 but otherwise rejected Zydus' argument that Relators' State FCA claims are time-limited. ECF No. 153 at 30-31.

Zydus respectfully requests reconsideration of this decision as it relates to the State FCAs of Connecticut, Georgia, Indiana, Minnesota, New Jersey, Oklahoma, and Rhode Island. Each of these States applies a presumption that a statute operates prospectively only unless the legislature directs otherwise, and there is no statutory language or legislative history indicating that these State FCAs apply retroactively:

- **Connecticut.** The Connecticut Supreme Court has held that “[t]he principles that govern retroactive application of legislative enactments are well-established. Except as to amending statutes that are procedural in their impact, there is a general presumption that legislation is intended to operate prospectively.” *Enfield Fed. Sav. & Loan Ass’n v. Bissell*, 440 A.2d 220, 221 (1981). There is no statutory language or legislative history suggesting that the Connecticut legislature intended the Connecticut False Claims Act to apply retroactively; to the contrary, the Connecticut legislature stated that the statute was effective on October 5, 2009. *See* 2009 Conn. Acts 5 (Sept. Spec. Sess.), § 181 (West). All Connecticut claims arising prior to October 5, 2009 should be dismissed.
- **Georgia.** The Georgia Constitution states that “[n]o bill of attainder, ex post factor law, retroactive law, or laws impairing the obligation of contract or making irrevocable grant of special privileges or immunities shall be passed.” Ga Const. art. 1, § 1, ¶ X. For this reason, the Georgia Supreme Court has held that “legislation which involves mere procedural or evidentiary changes may operate retrospectively; however, legislation which affects substantive rights may operate only prospectively.” *Fowler Props., Inc. v. Dowland*, 646 S.E.2d 197, 200 (Ga. 1997). Clearly, the Georgia False Medicaid Claims Act affects substantive rights, and there is no statutory language or legislative history suggesting that the Georgia

legislature intended the statute to apply retroactively. To the contrary, the legislature stated that the statute “shall become effective upon its approval by the Governor or upon its becoming law without such approval,” which occurred on May 24, 2007. *See* 2007 Ga. Laws Act 220, § 4 (West). All Georgia claims arising prior to May 24, 2007 should be dismissed.

- **Indiana.** In Indiana, “[a]bsent an express indication otherwise, [courts applying Indiana law] presume that the legislature intended that the statute be applied prospectively only.” *Robinson v. Valladares*, 738 N.E. 2d 278, 281 (Ind. Ct. App. 2000). There is no statutory language or legislative history suggesting that the Indiana legislature intended the Indiana False Claims and Whistleblower Protection Act to apply retroactively; to the contrary, the Indiana legislature stated that the statute was effective on July 1, 2005. *See* 2005 Ind. Legis. Serv. P.L. 222-2005, § 23 (West). All Indiana claims arising prior to July 1, 2005 should be dismissed.
- **Minnesota.** The Minnesota Supreme Court has held that “Minnesota laws are presumed to have no retroactive effect unless clearly and manifestly intended by the legislature.” *Mason v. Farmers Ins. Cos.*, 281 N.W.2d 344, 348 (Minn. 1979). There is no statutory language or legislative history suggesting that the Minnesota legislature intended the Minnesota False Claims Act to apply retroactively; to the contrary, the Minnesota legislature stated that the statute “is effective July 1, 2010.” 2009 Minn. Sess. Law Serv. Ch. 101, § 25 (West).
- **New Jersey.** In New Jersey, there is a presumption against retroactive application of statutes subject to three exceptions: “(1) the Legislature has expressed, either explicitly or implicitly, its intent that the statute apply retroactively; (2) the statute is ‘curative’; or (3) the expectations of the parties warrant the retroactive application of the statute.” *Olkusz v. Brown*, 951 A.2d 1069, 1073 (N.J. Super. Ct. App. Div. 2008). None of these exceptions apply to the New Jersey False Claims Act; to the contrary, the New Jersey legislature stated that the statute was to “take effect on the 60th day after enactment” (or on March 13, 2008). *See* 2007 N.J. Sess. Law Serv. Ch. 265, § 19 (West). All New Jersey claims arising prior to March 13, 2008 should be dismissed.
- **Oklahoma.** The Oklahoma Supreme Court has held that “[a]bsent a plain legislative intent to the contrary, statutes are generally presumed to operate prospectively only.” *Cole v. Silverado Foods, Inc.*, 78 P.3d 542, 546 (Okla. 2003). There is no statutory language or legislative history

suggesting that the Oklahoma legislature intended the Oklahoma Medicaid False Claims Act to apply retroactively; to the contrary, the legislature stated that the statute “shall become effective November 1, 2007.” See 2007 Okla. Sess. Law Serv. Ch. 137, § 9 (West). All Oklahoma claims arising prior to November 1, 2007 should be dismissed.

- **Rhode Island.** The Rhode Island Supreme Court has held that it “presumes that statutes and their amendments operate prospectively unless there is a clear, strong language or a necessary implication that the General Assembly intended to give the statute retroactive effect.” *Direct Action for Rights & Equal. v. Gannon*, 819 A.2d 651, 658 (R.I. 2003). There is no statutory language or legislative history suggesting that the Rhode Island legislature intended the Rhode Island False Claims Act to apply retroactively; to the contrary, the legislature stated that the statute “shall become effective ... on February 15, 2008.” See 2007 R.I. Laws Ch. 07-73, art. 18, § 8 (West). All Rhode Island claims arising prior to February 15, 2008 should be dismissed.

III. RELATORS LACK STANDING TO PROCEED WITH THEIR STATE FCA CLAIMS.

In its motion to dismiss, Zydus argued that Relators could not proceed with their State FCA claims because, at that time, none of the States had filed with the Court statutorily-required notices declining intervention in this action. ECF No. 101-1 at 33. In response, Relators referred the Court to the notice declining intervention filed by the United States in January 2014 but did not otherwise argue that the States had complied with State FCA requirements. See ECF No. 106 at 33-34. In September 2016, after the parties completed briefing of Zydus’s motion, some (but not all) of the States filed notices declining intervention. See ECF Nos. 120-140, 142-144, 146.

In its Opinion, the Court observed that the notice declining intervention filed by the United States “does not comply with the procedures set forth in each [State’s] false claims act.” ECF No. 153 at 29. However, the Court held that, in light of the notices filed by the States in September 2016, it would allow Relators’ State FCA claims to proceed. (*Id.* at 30.) In arriving at this conclusion, the Court appears to have overlooked two issues.

A. Three States—Georgia, Hawaii, and Rhode Island—Have Not Filed Notices Declining Intervention.

The Court’s observation that, in September 2016, each of the States had filed with the Court “formal notice” declining intervention, ECF No. 153 at 29-30, is not correct. Three States—Georgia, Hawaii, and Rhode Island—still have not filed the required notices. Under the applicable statutes², Relators lack standing to proceed with their Georgia, Hawaii, and Rhode Island claims.

² See Ga. Code § 49-4-168.2(c)(4) (“Before the expiration of the 60 day period [following service of the complaint] or any extensions obtained under paragraph (3) of this subsection, the Attorney General shall: . . . (B) Notify the court that it declines to take over the civil action, in which case the person bringing the civil action shall have the right to proceed with the civil action”); Haw. Stat. § 661-25(d) (“Before the expiration of the sixty-day period or any extension, the State shall: . . . (s) Notify the court that it declines to take over the action, in which case the person bringing the action shall have the right to conduct the action and the seal shall be lifted.”); R.I. Gen. Laws § 9-1.1-4(b)(4) (“Before the expiration of the sixty (60) day period or any extensions obtained under paragraph (3), the state shall: . . . (ii) Notify the court that it declines to take over the action, in which case the person bringing the action shall have the right to conduct the action.”).

B. The Notices Declining Intervention Filed by 24 States and the District of Columbia Do Not Comply with State FCA Requirements.

Relators lack standing to proceed with their other State FCA claims because the notices declining intervention filed in September 2016 do not comply with statutory requirements. All of these notices are more than five years late.

Each State FCA includes similar requirements. First, upon filing a complaint, the relator is required to serve a copy of the complaint on the State Attorney General or other State official.³ Second, unless the State elects to intervene in and take over

³ **California:** Cal. Gov't Code § 12652(c)(3) ("On the same day as the complaint is filed pursuant to paragraph (2), the qui tam plaintiff shall serve by mail with 'return receipt requested' the Attorney General with a copy of the complaint and a written disclosure of substantially all material evidence and information the person possesses."); **Connecticut:** Conn. Gen. Stat. § 17b-301d(b) ("A copy of the complaint and a written disclosure of substantially all material evidence and information the person possesses shall be served on the state by serving the Attorney General in the manner proscribed in section 52-64."); **Colorado:** Colo. Stat. § 25.5-4-306(2)(b) ("A copy of the complaint and written disclosure of substantially all material evidence and information the relator possesses shall be served on the state pursuant to rule 4 of the Colorado rules of civil procedure."); **Delaware:** 6 Del. Code § 1203(b)(2) ("A copy of the complaint and written disclosure of substantially all material evidence and information the private party possesses shall be served on the Department of Justice pursuant to Rules 4 and 5 of the Superior Court Civil Rules."); **District of Columbia:** D.C. Code § 2-381.03(b)(3) ("On the same day as the complaint is filed pursuant to paragraph (2) of this subsection, the qui tam plaintiff shall serve the Attorney General for the District of Columbia by mail, return receipt requested, with a copy of the complaint and a written disclosure of substantially all material evidence and information the person possesses."); **Florida:** Fla. Stat. § 68.083(3) ("Immediately upon the filing of the complaint, a copy of the complaint and written disclosure of substantially all material evidence and information the person possesses shall be served on the Attorney General, as head of the department, and on the Chief Financial Officer, as head of the Department of Financial Services, by registered mail, return receipt requested."); **Georgia:** Ga. Code § 49-4-168.2(c)(1) ("A copy of the complaint and written disclosure of substantially all material evidence and information the person possesses shall be served on the Attorney General"); **Hawaii:** Haw. Stat. § 661-25(b) ("A copy of the complaint and written disclosure of substantially all material evidence and information the person possesses shall be served on the State in accordance with the Hawaii rules of civil procedure."); **Illinois:** 740 Ill. Comp. Stat. 175/4(b)(2) ("A copy of the complaint and written disclosure of substantially all

material evidence and information the person possesses shall be served on the State.”); **Indiana:** Ind. Code § 5-11-5.5-4(c) (“A person who brings an action under this section shall serve: (1) a copy of the complaint; and (2) a written disclosure that describes all relevant material evidence and information the person possesses; on both the attorney general and inspector general.”); **Iowa:** Iowa Code § 685.3(2)(b) (“A copy of the complaint and written disclosure of substantially all material evidence and information the person possesses shall be served on the attorney general pursuant to the Iowa rules of civil procedure.”); **Maryland:** Md. Code, Health-Gen. § 2-604(a)(3)(i) (“The person shall serve on the State a copy of the complaint and a written disclosure of substantially all material evidence and information that the person possesses, in accordance with the provisions of Title 2 of the Maryland Rules for serving process on the State.”); **Massachusetts:** Mass. Gen. Laws ch. 12 § 5C(3) (“When a relator brings an action under said sections 5B to 50, inclusive, a copy of the complaint and written disclosure of substantially all material evidence and information the relator possesses shall be served on the attorney general pursuant to Rule 4(d)(3) of the Massachusetts Rules of Civil Procedure.”); **Michigan:** Mich. Comp. Laws § 400.610a(2) (“At the time of filing the complaint, the person shall serve a copy of the complaint on the attorney general and shall disclose, in writing, substantially all material evidence and information in the person’s possession supporting the complaint to the attorney general.”); **Minnesota:** Minn. Stat. § 15C.05(e) (“If a complaint is filed under this section, the plaintiff shall serve a copy of the complaint on the prosecuting attorney in accordance with the Minnesota Rules of Civil Procedure and at the same time shall serve a written disclosure of all material evidence and information the plaintiff possesses.”); **Montana:** Mont. Code § 17-8-406(2) (“A copy of the complaint and written disclosure of substantially all material evidence and information that the person possesses must be served on the government attorney pursuant to Rule 4(c)(2)(C), (c)(2)(D), and (d) through (s) Montana Rules of Civil Procedure.”); **Nevada:** Nev. Rev. Stat. § 357.080(5) (“On the date the private plaintiff files a complaint, he or she shall send a copy of the complaint to the Attorney General by mail with return receipt requested. The private plaintiff shall send with each copy of the complaint a written disclosure of substantially all material evidence and information he or she possesses.”); **New Hampshire:** N.H. Rev. Stat. § 167:61-c(II)(c) (“A copy of the complaint and written disclosure of substantially all material evidence and information the relator possesses shall be served on the state in accordance with the New Hampshire rules of civil procedure.”); **New Jersey:** N.J. Stat. § 2A:32C-5(d) (“Immediately upon filing of the complaint, the plaintiff shall serve by registered mail, return receipt requested, the Attorney General with a copy of the complaint and written disclosure of substantially all material evidence and information the person possesses.”); **New Mexico:** N.M. Stat. § 44-9-5(C) (“On the same day as the complaint is filed, the qui tam plaintiff shall serve the attorney general, and the political subdivision, if applicable, with a copy of the complaint and written disclosure of substantially all material evidence and information the qui tam plaintiff possesses.”); **New York:** N.Y. State Fin. Law § 190(2)(b) (“A copy of the complaint and written disclosure of substantially all material evidence and information the person possesses shall be served on the state pursuant to subdivision one of section three hundred seven of the civil practice laws and rules.”); **North Carolina:** N.C. Gen. Stat. § 1-608(b)(2) (“A copy of the complaint and written disclosure of substantially all material evidence and information the person possesses shall be served on the Attorney General pursuant to applicable rules of the North Carolina Rules of Civil Procedure.”); **Oklahoma:**

the action, the State Attorney General or other State official must file with the court a notice declining intervention within a period of time after receiving the complaint, typically 60 days.⁴

Okla. Stat. tit. 63 § 5053.2(B)(2) (“A copy of the complaint and written disclosure of substantially all material evidence and information the person possesses shall be served on the state pursuant to Section 2004 of Title 12 of the Oklahoma Statutes.”); **Rhode Island:** R.I. Gen. Laws § 9-1.1-4(b)(2) (“A copy of the complaint and written disclosure of substantially all material evidence and information the person possesses shall be served on the state upon the attorney general.”); **Tennessee:** Tenn. Code § 71-5-183(b)(2) (“A copy of the complaint and written disclosure of substantially all material evidence and information the person possesses shall be served on the state.”); **Virginia:** Va. Code § 8.01-216.5(B) (“A copy of the complaint and written disclosure of substantially all material evidence and information the person possesses shall be served on the Commonwealth.”); **Wisconsin:** Wis. Stat. § 20.931(5)(b) (“The plaintiff shall serve upon the attorney general a copy of the complaint and documents disclosing substantially all material evidence and information that the person possesses.”).

⁴ Six jurisdictions depart from the rule that the State official has 60 days (absent any extension) to notify the court of its election to intervene and take over the action or decline intervention: the District of Columbia (180 days), Indiana (120 days), Massachusetts (120 days), Michigan (90 days), North Carolina (120 days), and Virginia (120 days). *See* D.C. Code § 2-381.03(b)(4); Ind. Code § 5-11-5.5-4(c), (e); Mass. Gen. Laws ch. 12 § 5C(4); Mich. Comp. Laws § 400.610a(3); N.C. Gen. Stat. § 1-608(b)(4); Va. Code § 8.01-216.5(D).

California: Cal. Gov’t Code § 12652(c)(6) (“Before the expiration of the 60-day period or any extensions obtained under paragraph (5), the Attorney General shall do either of the following: (A) Notify the court that it intends to proceed with the action, in which case the action shall be conducted by the Attorney General and the seal shall be lifted. (B) Notify the court that it declines to proceed with the action, in which case the seal shall be lifted and the qui tam plaintiff shall have the right to conduct the action.”); **Connecticut:** Conn. Gen. Stat. § 17b-301d(b) (“The complaint shall be filed in camera, shall remain under seal for at least sixty days ... Prior to the expiration of the time during which the complaint remains under seal, the Attorney General shall: (1) Proceed with the action in which case the action shall be conducted by the Attorney General, or (2) notify the court that the Attorney General declines to take over the action in which case the person bringing the action shall have the right to conduct the action.”); **Colorado:** Colo. Stat. § 25.5-4-306(2)(d) (“Before the expiration of the sixty-day period pursuant to paragraph (b) of this subsection (2) or any extensions obtained under paragraph (c) of this subsection (2), the state shall (i) Proceed with the action, in which case the state shall conduct the action; or (ii) Notify the court that it declines to take over the action, in which case the relator shall have the right to conduct the action.”); **Delaware:** 6 Del. Code § 1203(b)(4) (“Before the expiration of the 60-day period or any extensions obtained under paragraph (b)(3) of this section, or within 20 days of being notified by the court that the seal has expired, the Department of Justice shall: (a) Proceed with the action, in which case the

action shall be conducted by the Department of Justice; or (b) Notify the court that it declines to take over the action, in which case the private party bringing the action shall have the right to conduct the action.”); **District of Columbia:** D.C. Code § 2-381.03(b)(4) (“Within 180 days after receiving a complaint alleging violations involving District funds, the Attorney General for the District of Columbia shall do either of the following: (A) Notify the court that he or she intends to proceed with the action, in which case the seal may be lifted unless, for good cause shown, the court continues the seal; or (B) Notify the court that he or she declines to take over the action, in which case the seal shall be lifted and the qui tam plaintiff shall have the right to conduct the action.”); **Florida:** Fla. Stat. § 68.083(6) (“Before the expiration of the 60-day period or any extensions obtained under subsection (5), the department shall: (a) Proceed with the action, in which case the action is conducted by the department on behalf of the state; or (b) Notify the court that it declines to take over the action, in which case the person bringing the action has the right to conduct the action.”); **Georgia:** Ga. Code § 49-4-168.2(4) (“Before the expiration of the 60 day period or any extensions obtained under paragraph (3) of this subsection, the Attorney General shall: (A) Proceed with the civil action, in which case the civil action shall be conducted by the Attorney General; or (B) Notify the court that it declines to take over the civil action, in which case the person bringing the civil action shall have the right to proceed with the action”); **Hawaii:** Haw. Stat. § 661-25(d) (“Before the expiration of the sixty-day period or any extension obtained, the State shall: (1) Proceed with the action, in which case the action shall be conducted by the State and the seal shall be lifted; or (2) Notify the court that it declines to take over the action, in which case the person bringing the action shall have the right to conduct the action and the seal shall be lifted.”); **Illinois:** 740 Ill. Comp. Stat. 175/4(b)(4) (“Before the expiration of the 60-day period or any extensions obtained under paragraph (3), the State shall: (A) proceed with the action, in which case the action shall be conducted by the State; or (B) notify the court that it declines to take over the action, in which case the person bringing the action shall have the right to conduct the action.”); **Indiana:** Ind. Code § 5-11-5.5-4(c), (e) (“the complaint shall remain under seal for at least one hundred twenty (120) days. ... Before the expiration of the time during which the complaint is sealed, the attorney general or the inspector general may: (1) intervene in the case and proceed with the action, in which case the attorney general or the inspector general shall conduct the action; or (2) elect not to proceed with the action, in which case the person who initially filed the complaint may proceed with the action.”); **Iowa:** Iowa Code § 685.3(d) (“Before the expiration of the sixty-day period or any extensions obtained under paragraph “c”, the state shall do one of the following: (1) Proceed with the action, in which case the action shall be conducted by the state. (2) Notify the court that the state declines to take over the action, in which case the qui tam plaintiff shall have the right to conduct the action.”); **Maryland:** Md. Code, Health-Gen. § 2-604(a)(6) (“Before the later of the expiration of the 60-day period during which the complaint remains under seal under paragraph (3)(ii)(1) of this subsection or any extension of the 60-day period obtained under paragraph (4) of this subsection, the State shall: (i) Intervene and proceed with the action in a court of competent jurisdiction within the State; or (ii) Notify the court that it will not intervene and proceed with the action.”); **Massachusetts:** Mass. Gen. Laws ch. 12 § 5C(4) (“Before the expiration of the initial 120 day period or any extensions obtained under paragraph (3), the attorney general shall; (i) assume control of the action, in which case the action shall be conducted by the attorney general; or (ii) notify the court that he declines to take over the action, in which case the relator shall have the right to conduct the

action.”); **Michigan:** Mich. Comp. Laws § 400.610a(3) (“Before the expiration of the later of 90 days after service of the complaint and related materials or any extension of the 90 days that is requested by the attorney general and granted by the court, the attorney general shall notify the court and the person initiating the action of 1 of the following: (a) That the attorney general will proceed with the action for this state and have primary responsibility for proceeding with the action. (b) That the attorney general declines to take over the action and the person initiating the action has the right to proceed with the action.”); **Minnesota:** Minn. Stat. § 15C.06(a) (“Within 60 days after receiving a complaint and disclosure under section 15C.05, the prosecuting attorney shall intervene or decline intervention or, for good cause shown, move the court to extend the time for doing so.”); **Montana:** Mont. Code § 17-8-406(3) (“Within 60 days after receiving the complaint and the material evidence and information, the government attorney may elect to intervene and proceed with the action or to notify the court that the government attorney declines to take over the action.”); **Nevada:** Nev. Rev. Stat. § 357.110(1), (2) (“Within 60 days after receiving a complaint and disclosure, the Attorney General or a designee of the Attorney General pursuant to NRS 357.070 may intervene and proceed with the action ... If the Attorney General or the Attorney General’s designee elects not to intervene, the private plaintiff may proceed with the action.”); **New Hampshire:** N.H. Rev. Stat. § 167:61-c(II)(e) (“Before the expiration of the 60-day period or any extension obtained, the state shall: (1) Proceed with the action, in which case the action shall be conducted by the state; or (2) Notify the court that it declines to take over the action, in which case the relator who initiated the proceeding may conduct the action.”); **New Jersey:** N.J. Stat. § 2A:32C-5(g) (“Before the expiration of the 60-day period or any extensions obtained under subsection f., the Attorney General shall: (1) file a pleading with the court that he intends to proceed with the action, in which case the action is conducted by the Attorney General and the seal shall be lifted; or (2) file a pleading with the court that he declines to proceed with the action, in which case the seal shall be lifted and the person bringing the action shall have the right to conduct the action.”); **New Mexico:** N.M. Stat. § 44-9-5(D) (“Before the expiration of the sixty-day period or any extensions of time granted by the court, the attorney general or political subdivision shall notify the court that the state or the political subdivision: (1) intends to intervene and proceed with the action; in which case, the seal shall be lifted and the action shall be conducted by the attorney general on behalf of the state or the political subdivision, or the political subdivision shall conduct the action on its own behalf; or (2) declines to take over the action; in which case the seal shall be lifted and the qui tam plaintiff may proceed with the action.”); **New York:** N.Y. State Fin. Law § 190(2)(c) (“Prior to the expiration of the sixty day period or any extensions obtained under paragraph (b) of this subdivision, the attorney general shall notify the court that he or she: (i) intends to file a complaint against the defendant on behalf of the people of the state of New York or a local government ... ; (ii) intends to intervene in such action, as of right, so as to aid and assist the plaintiff in the action ...); N.Y. State Fin. Law § 190(2)(f) (“If the state declines to participate in the action or to authorize participation by a local government, the qui tam action may proceed subject to judicial review under this section, the civil practice law an rules, and other applicable law.”); **North Carolina:** N.C. Gen. Stat. § 1-608(b)(4) (“Before the expiration of the 120-day period or any extensions obtained under subdivision (3) of this subsection, the State shall: (a) Proceed with this action, in which case the action shall be conducted by the State; or (b) Notify the court that it declines to take over the action, in which case the person bringing the action shall have the right to conduct the

Take, as one example, the California False Claims Act, Cal. Gov't Code §§ 12650-12656. The requirements applicable to a *qui tam* action under the California statute are set out in section 12652(c). As indicated above, Relators were required to serve a copy of the Complaint by mail on the California Attorney General on June 21, 2011, the same day they filed their Complaint in the Eastern District of Texas. *See* Cal. Gov't Code § 12652(c)(3).⁵ The California Attorney General then had 60 days to either (i) intervene in and take over the action or (ii) file with the Court a

action.”); **Oklahoma:** Okla. Stat. tit. 63 § 5053.2(B)(4) (“Before the expiration of the sixty-day period or any extensions obtained under paragraph 3 of this subsection, the state shall: (a) proceed with the action, in which case the action shall be conducted by the state, or (b) notify the court that it declines to take over the action, in which case the person bringing the action shall have the right to conduct the action.”); **Rhode Island:** R.I. Gen. Laws § 9-1.1-4(b)(4) (“Before the expiration of the sixty (60) day period or any extensions obtained under paragraph (3), the state shall: (i) Proceed with the action, in which case the action shall be conducted by the state; or (ii) Notify the court that it declines to take over the action, in which case the person bringing the action shall have the right to conduct the action.”); **Tennessee:** Tenn. Code § 71-5-183(b)(4) (“Before the expiration of the sixty-day period or any extensions obtained under subdivision (b)(3), the state shall: (A) Proceed with the action, in which case the action shall be conducted by the state; or (B) Notify the court that it declines to take over the action, in which case the person bringing the action shall have the right to conduct the action.”); **Virginia:** Va. Code § 8.01-216.5(D) (“Before the expiration of the 120-day period or any extensions obtained under subsection C, the Commonwealth shall proceed with the action, in which case the action shall be conducted by the Commonwealth, or notify the court that it declines to take over the action, in which case the person bringing the action shall have the right to prosecute the action.”); **Wisconsin:** Wis. Stat. § 20.931(5)(b), (d) (“Except as provided in par. (c), the complaint shall remain under seal for a period of 60 days from the date of filing ... Before the expiration of the period during which the complaint remains under seal, the attorney general shall do one of the following: (1) Proceed with the action or an alternate remedy under sub. (10), in which case the action or proceeding under sub. (10) shall be prosecuted by the state. (2) Notify the court that he or she declines to proceed with the action, in which case the person bringing the action may proceed with the action.”).

⁵ “On the same day as the complaint is filed pursuant to paragraph (2), the *qui tam* plaintiff shall serve by mail with ‘return receipt requested’ the Attorney General with a copy of the complaint and a written disclosure of substantially all material evidence and information the person possesses.” Cal. Gov't Code § 12652(c)(3).

notice declining intervention.⁶ *See* Cal. Gov’t Code § 12652(c)(6).⁷ But the California Attorney General did neither. Rather, she waited more than five years—until September 19, 2016—to file with the Court a notice declining intervention. *See* ECF No. 121.

There is no dispute that the States have failed to comply with State FCA requirements. Each of the States, like California, filed the required notice more than five years after the applicable deadlines. *See* ECF Nos. 120-140, 142-144, 146. This indicates either that (i) Relator failed to serve the States with a copy of the Complaint as required, or (ii) the States failed to abide by State FCA requirements. Whatever the reason, this is an egregious failure to comply with well-established State FCA requirements.

Because Relators or the States have not complied with State FCA requirements, Relators have no standing to proceed with their State claims. The State FCAs are the sole source of Relators’ authority to assert State claims. For each State, a relator’s “right to conduct the action” is conditioned on compliance with

⁶ The California statutes allows the Attorney General to move the court for an extension of this 60-day period. *See* Cal. Gov’t Code § 12652(c)(5). However, there is no indication in the docket or elsewhere that the California Attorney General filed such a motion.

⁷ “Before the expiration of the 60-day period or any extensions obtained under paragraph (5), the Attorney General shall do either of the following: (A) Notify the court that it intends to proceed with the action, in which case the action shall be conducted by the Attorney General and the seal shall be lifted. (B) Notify the court that it declines to proceed with the action, in which case the seal shall be lifted and the qui tam plaintiff shall have the right to conduct the action.” Cal. Gov’t Code § 12652(c)(6).

statutory requirements, including a timely notice declining intervention.⁸ *See, e.g.,* Cal. Gov’t Code § 12652(c)(6) (stating that upon timely notice by the California Attorney General to the court declining to proceed with the action, “the seal shall be lifted and the *qui tam* plaintiff shall have the right to conduct the action.”). *See also* *United States ex rel. Bogart v. King Pharms.*, 414 F. Supp. 2d 540, 543 (E.D. Pa. 2006) (denying the relator’s request for a share of settlement proceeds based on fifteen-month delay in serving States with the complaint and observing that “the Relator would not even have the standing to bring a claim on behalf of the States absent their *qui tam* statutes.”). For this reason, as the Court noted in its Opinion, Judge Linares concluded in *United States ex rel. Simpson v. Bayer Corp.*, No. 05-3895, 2014 WL 1418293, at *11 (D.N.J. Apr. 11, 2014), that certain States’ failure to file notices declining intervention warranted dismissal of the relator’s State FCA claims as premature. *See* ECF No. 153 at 29.

Zydus respectfully requests that the Court dismiss Relators’ State FCA claims without prejudice and instruct Relators to re-file their complaint and comply with all State FCA requirements. This is a complex and consequential action: Relators seek

⁸ It is well-settled that a party pursuing a statutory remedy must comply with all of the procedures set out in the statute. *See, e.g., United States ex rel. Tex. Portland Cement Co. v. McCord*, 233 U.S. 157, 162 (1914) (where a statute creates a new remedy, as the State FCAs do, “upon well-settled principles the limitations upon such liability become a part of the right conferred, and compliance with them is made essential to the assertion and benefit of the liability itself.”).

from Zydus tens of millions of dollars in alleged damages based on State Medicaid reimbursements for Zydus's generic drugs. The Court should clarify any issue concerning Relators' standing now, before the parties begin expensive and time-consuming discovery.

CONCLUSION

For the foregoing reasons, Defendant Zydus Pharmaceuticals (USA), Inc. respectfully requests that the Court grant its motion for reconsideration.

Dated: May 10, 2017

s/ Stephen M. Orlofsky

BLANK ROME LLP

A Pennsylvania LLP

STEPHEN M. ORLOFSKY

NICHOLAS C. HARBIST

DAVID C. KISTLER

New Jersey Resident Partners

301 Carnegie Center, 3rd Floor

Princeton, NJ 08540

Telephone: (609) 750-2646

Facsimile: (609) 897-7286

KIRKLAND & ELLIS LLP

JENNIFER G. LEVY (*pro hac vice*)

JASON R. PARISH (*pro hac vice*)

655 Fifteenth Street, NW

Washington, DC 20005

Telephone: (202) 879-5000

Facsimile: (202) 879-5200